

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appln. No. : 10/627,791
Applicant : Steve Bigus et al.
Filed : July 25, 2004
Title : SHEATH FOR SELF-EXPANDING STENTS
Art Unit : 3738
Confirmation No. : 2675
Examiner : David J. Isabella

Docket No.: : ACS-64940 (2238XD) Los Angeles, California
Customer No. : 24201 March 8, 2007

MAIL STOP APPEAL BRIEF-PATENTS
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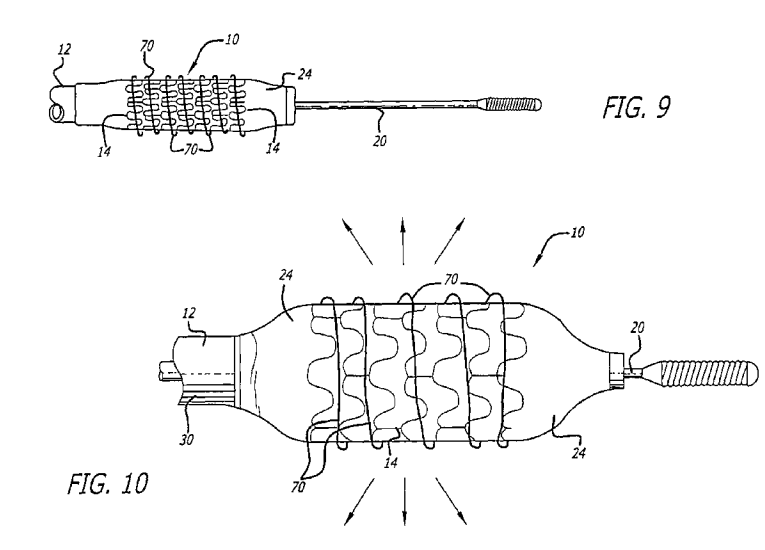
PRE-APPEAL BRIEF REQUEST FOR REVIEW

INTRODUCTION

The present invention relates to a bio-compatible or bio-absorbable sheath, lining, or filament positioned on or in a stent. The bio-compatible or bio-absorbable material is designed to be implanted in the body along with the stent. After implantation, the material may be absorbed into the body, such as where the material is a bio-absorbable material that dissolves over a period of time.

In one embodiment of the invention, a bio-absorbable or bio-compatible filament is wound through or around an expandable stent. The filament may have sufficient strength to help in constraining the stent in an unexpanded configuration. Such a filament may still have sufficient weakness to permit the stent to be expanded via the application of a force, such as via expansion of a balloon catheter when the stent is positioned on the balloon. Figures 9 and 10 from the patent application are reproduced below to illustrate this embodiment having a filament

70 wrapped around a stent 14 and delivered to the intraluminal lesion on an expandable balloon 24.



Expansion of the stent may be achieved by applying sufficient force to cause the filament to break or otherwise fail or relax. Expansion of the stent may be achieved by changing the configuration of the filament, such as by pulling or pushing, proximally or distally, on the filament until it no longer provides sufficient restraint to prevent the stent from expanding. The filament may be formed from various materials, including polymers. The filament may comprise one or more therapeutic agents, such as a drug useful in treating arterial walls.

Such a filament may be bonded to the delivery catheter and/or the stent, such as where a polymer filament is heat-bonded in a tightly-coiled position around the stent. During stent deployment, which may be achieved through inflation of a balloon catheter, the bonding of the filament to the stent and/or delivery catheter may fail, in whole or in part, loosening the tightness of the filament around the stent and permitting the stent to expand.

The filament may be used to constrain self-expanding stents to prevent their expanding prior to the desired time and position for stent deployment. The filament may also be used with non-self-expanding stents, such as balloon-expandable stents, to help to retain the stent on a delivery system, such as a delivery catheter.

In a further embodiment of the invention, the bio-compatible and/or bio-absorbable material forms a sheath and/or coating that surrounds the stent, in whole or in part. Like the

filament, the sheath and/or coating may have sufficient strength to help in constraining the stent in an unexpanded configuration, and may still have sufficient weakness to permit the stent to be expanded by applying sufficient force to cause the sheath to break or otherwise fail and/or relax. The sheath and/or coating may be formed from various materials, including polymers, and may comprise one or more therapeutic agents. In the case of a coating that is bonded to the stent, the coating may be applied to the inner or outer surface of the stent.

NOTICE OF APPEAL

A Notice of Appeal from the final Office Action of December 8, 2006 is being filed concurrently herewith along with the appropriate fee.

ISSUES ON APPEAL

1. In the first and final Office actions, the examiner rejected claims 1, 5, 6, 11 and 24 under 35 U.S.C. § 102(e) over U.S. Patent No. 6,878,161 (Lenker). The examiner on page 4 of the final Office action agrees that claims 1, 5, 6, 11, and 24 have a priority date back to June 29, 2001. This is prior to the April 25, 2002 filing date of the Lenker `161 reference. Lenker `161 is therefore not prior art to claims 1, 5, 6, 11, and 24. The rejection of these claims based on Lenker `161 should be withdrawn.

2. The examiner asserts that the subject matter supporting his rejection found in Lenker `161 “is fully disclosed” in its great grandparent patent (U.S. Patent No. 5,843,158 (Lenker)), and that subject matter should be afforded the Lenker `158 priority/filing date. Lenker `161 is a C-I-P of Lenker `158 and it appears that the subject matter in Lenker `161 relied upon by the examiner for the rejection was new matter added to the C-I-P, which new matter cannot date back to the Lenker `158 filing date.

3. The examiner’s reliance on Lenker `158 is based on six full columns of text. Applicant has read through these passages and found no support for the examiner’s rejections.

ARGUMENT

Issue 1: In the first and final Office actions, the examiner rejected claims 1, 5, 6, 11 and 24 under 35 U.S.C. § 102(e) over U.S. Patent No. 6,878,161 (Lenker). The examiner on page 4 of the final Office action agrees that claims 1, 5, 6, 11, and 24 have a priority date back to June 29, 2001, which is the filing date of the parent application. This is prior to the April 25, 2002 filing date of the Lenker `161 reference. Lenker `161 is therefore not prior art to claims 1, 5, 6, 11, and 24. The rejections of these claims based on Lenker `161 should be withdrawn.

Issue 2: On page 4 of the final Office action, the examiner asserts that the subject matter supporting the rejections based on Lenker `161 “is fully disclosed” in its great grandparent (U.S. Patent No. 5,843,158 (Lenker)) so that the Lenker `161 subject matter should be afforded the earlier Lenker `158 filing/priority date.

Lenker `161 is a continuation-in-part patent. The examiner’s 102(e) rejection relies substantially on Figs. 1A, 1B, 2A, 2B, and 2C and their associated descriptions in the specification in Lenker `161. However, the drawings labeled Figs. 1A, 1B, 2A, 2B, 2C and those five figure numbers of Lenker `161 do not appear anywhere in the great grandparent Lenker `158. Since the later Lenker `161 is a C-I-P and a great grandchild of Lenker `158, it is highly likely that Figs. 1A, 1B, 2A, 2B, 2C and their associated descriptions in the specification the examiner is relying on are new matter added in the C-I-P Lenker `161.

The new matter that the examiner relies upon in Lenker `161 therefore cannot have the priority date of its great grandparent Lenker `158. If the subject matter in Lenker `161 cannot date back to prior to June 29, 2001, which is the filing date of the parent application, then as demonstrated above, Lenker `161 must be withdrawn as prior art against claims 1, 5, 6, 11, and 24.

Issue 3: On page 4 of the final Office action, to support the rejection of the claims in view of Lenker `158 (indirectly through Lenker `161), the examiner cites six full columns of text in Lenker `158 (cols. 4, 5, 7, 9, 12, and 14). Applicant has read through these passages and found no support for the examiner’s rejections. Therefore, even if Lenker `158 were cited in the

102(e) rejection, the teaching in the six enumerated columns do not disclose the claimed invention.

In conclusion, since the subject matter of Lenker `161 relied upon by the examiner for the rejection do not date back to Lenker `158, and since Lenker `161 is not prior art, the rejections based on this reference are unsupported and should be withdrawn. Furthermore, even if Lenker `158 were cited in the 102(e) rejection, the teaching in the six cited columns of this reference do not disclose the claimed invention.

Respectfully submitted,
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